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EXAMINER

KOSAR, AARON J

ART UNIT	PAPER NUMBER
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1609

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/20/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/649,742

Applicant(s)

KAIMAL ET AL.

Examiner

Aaron J. Kosar

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 9/29/2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. 09/207,056.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Specification

1. The disclosure is objected to because of the following informalities: The value, 2.Sg, appears to be a typographical error of 2.5g (page 10, line 18). Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "*reduced-calorie fat composition*" in claims 1-11 is a relative term which renders the claim indefinite. The term "*reduced-calorie*" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The term "*reduced*" implies a benchmark, standard, or reference-caloric fat composition to be defined; however, the claims and specification list fat-replacers and examples (pages 2-3, ¶ 0007 and 0010; page 16, lines 7-9), but do not present a definition of the threshold for establishing what constitutes "*reduced*".
4. Claims 1-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the

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invention. Applicant claims a weight percent (wt%) for each fatty acid. This value may refer to the *relative weight percent* of the fatty acid compared to the total of the fatty acid component in a more complex composition. In the alternative, the value may refer to the *absolute weight percent* relative to the total composition consisting of the itemized fatty acids. Both are reasonable interpretations of the claims; therefore it is not clear as to what the metes and bounds are for each of the claims. This rejection affects all the dependent claims equally. Furthermore, claim 4 by similar argument is also rejected for the indefiniteness introduced by the term *wt%*.

5. Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant claims an *expected* TAG composition, as opposed to claiming a TAG composition. Specifically, it would be reasonable to interpret an *expected* TAG such as the component BOS to define either isolated BOS separated by HPLC or, in the alternative, BOS as a representative of the inseparable group BOS, OBS, and OSB. It is unclear what are the metes and bounds of the actual composition and one of ordinary skill would not know what is being claimed.

6. Claims 4-10 recite the limitation "residue" in claim 4 (page 26, lines 2, 18—20); claims 5, 6, and 7 (page 27, lines 22, 25, and 27); and claims 8-10 (page 27, lines 2, 5, and 8). There is insufficient antecedent basis for this limitation in the claim. As a result the scope of each of the claims are rendered indeterminate. Lacking antecedent basis, the term can be broadly and reasonably be interpreted to comprise, among other compounds, the compound itself - such as "palmitic acid *and residues thereof*" may comprise "palmitic acid".

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7. Claim 11 contains the trademark/trade name LIPOZYME. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe a lipase (EC 3.1.1.3) and, accordingly, the identification/description is indefinite.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the

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reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

9. Claim 11 is rejected under 35 U.S.C. 102(b) as being anticipated by CAIN (USPAT 5654018). Claim 11 claims a fat composition product by the process of esterification of edible oil(s) with 1,3-dibehenin. While CAIN (Claim 1) claims a process for producing a "SUS" triglyceride composition which involves a different process with different manipulations and different recited steps than the process of the presently claimed invention - such as in the case where Cain's process results in the SUS product 2-oleo 1,3-dibehenin (BOB) - the product of Cain's process would still be identical in structure to the product produced by the process of the presently claimed process of claim 11. See MPEP 2113.

10. Claim 5-8 are rejected under 35 U.S.C. 102(b) as being anticipated by SCHWOPPE (USPAT 2954348). Claim 5 of the presently claimed invention claims a chemical composition comprising *palmitic acid, stearic acid, linoleic acid, arachidic acid, behenic acid, lignoceric acid, and residues thereof*. This combination, however, has been disclosed in Schwoppe wherein compositions are disclosed which may comprise palmitic, stearic, linoleic, arachidic, behenic, lignoceric acids, and combinations thereof (column 5, lines 1- 15).

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. Claims 7-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwoppe, *et al* (USPAT 2954348). The present application claims further limitations of claim 5, namely:

- a. 29.8-52.5% (w/w) behenic acid,
- b. 5-41% (w/w) linoleic acid
- c. 24.8-44.6% (w/w) linoleic acid
- d. 33-60% (w/w) linoleic acid

Although Schwoppe does not teach a method of using a composition comprising the specifically claimed concentration of the compounds for claims 7-10 (ranges *a-d*, *supra*), absent evidence to the contrary, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have optimized multi-component compositions for linoleic acid and behenic acid. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aaron J. Kosar whose telephone number is (571) 270-3054. The examiner can normally be reached on Monday-Thursday, 7:30AM-5:00PM, ALT. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mary Mosher can be reached on (571) 272-0235. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Aaron Kosar
Patent Examiner



MARY MOSHER
SUPERVISORY PATENT EXAMINER